

Clinical Decision Support Project

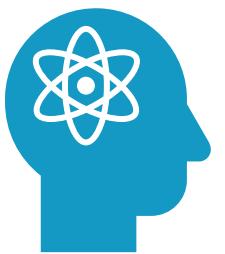
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07 February 2022*

Expanding the Boundaries of Space Medicine and Technology

- **Clinical Decision Support (CDS) Project Purpose and Objectives**
- **Defining a Clinical Decision Support System (CDSS) for Exploration**
 - What is a CDSS?
 - What does a CDSS do?
- **CDS Model**
 - Revised CDSS ConOps
 - Revised CDSS activity diagrams
 - Baseline requirements
- **CDS Project Documentation**
- **Summary and Conclusion**

- **NASA-STD-3001, Volume 1, Rev B** presents the in-mission medical care requirement: 'Means of providing autonomous medical care and advanced life support.'
- Computational and data resources will play an important role in maintaining crew health, wellness and performance where the crew will need to be more self-reliant.
 - Communication lags (~ 20min each way on a Mars mission)
 - Communication blackouts, planned and unplanned
 - No resupply
 - No evacuation
 - Potential limited knowledge, skills and ability (KSA)
 - Skills erosion over time
 - Crew time limited to identify symptoms, collect data, apply solutions and problem solve
- **Paradigm shift in Medical Operations**



ExMC Element Risk:

Risk of Adverse Health Outcomes and Decrements in Performance Due to Medical Conditions that occur in Mission, as well as Long Term Health Outcomes Due to Mission Exposures

Clinical Decision Support (CDS) Project Need:

ExMC Gap Medical-701: We need to increase inflight medical capabilities and identify new capabilities that (a) maximize benefit and/or (b) reduce “costs” on human system/mission/vehicle resources.

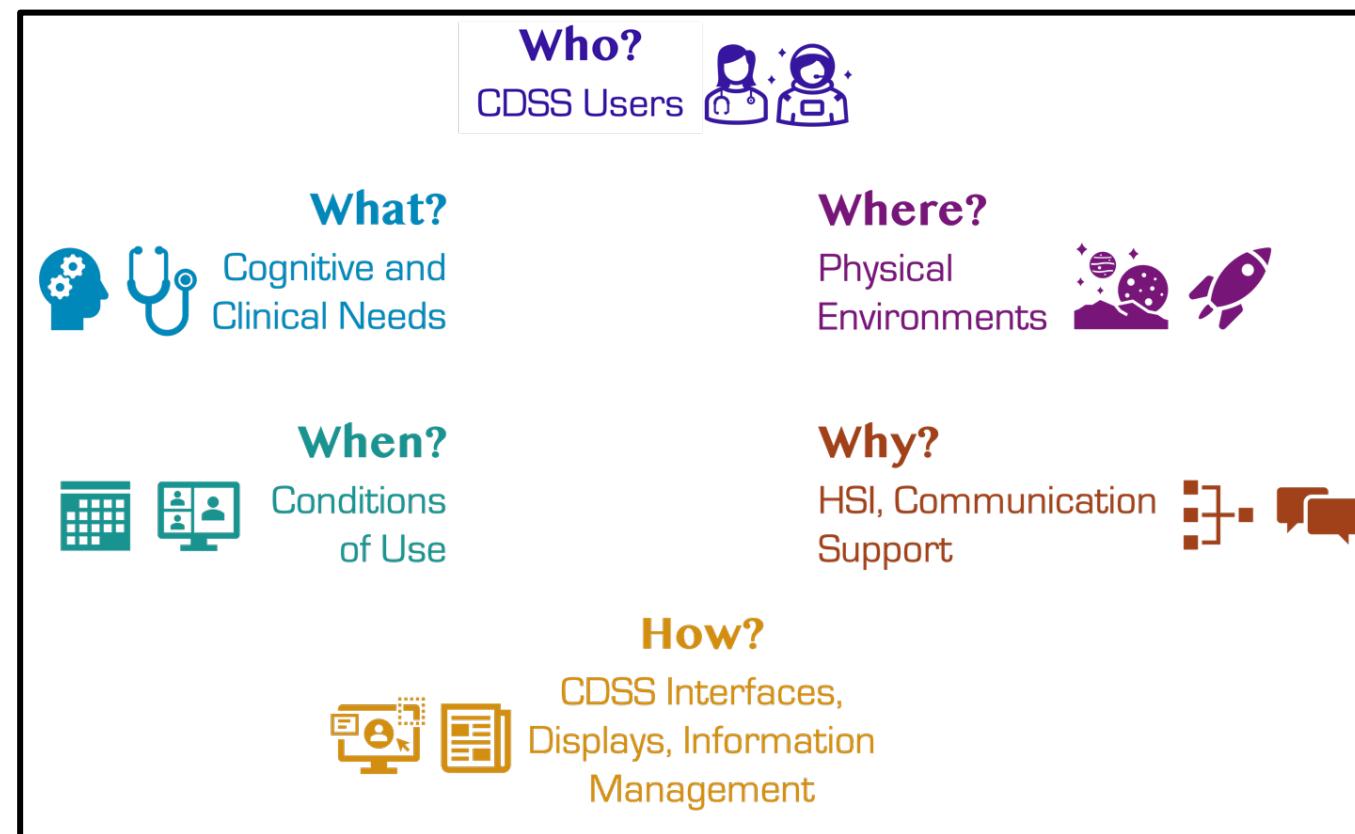
CDS Project Goal:

The aim of the CDS project was to [develop and provide recommended functional requirements](#) for an in-vehicle CDSS that [acts as an assistant](#) for delivering optimal health and performance and medical care during long-term, deep-space exploration missions.

CDSS Defined

- **What is a CDSS?**

- It's a **software tool** on a laptop and/or onboard system that interacts with the crew, databases (e.g., medical/clinical procedure, pharmacy, wellness, schedule), instruments (e.g., ultrasound, automated external defibrillator or AED, blood labs), and vehicle systems (e.g., environmental, communication).

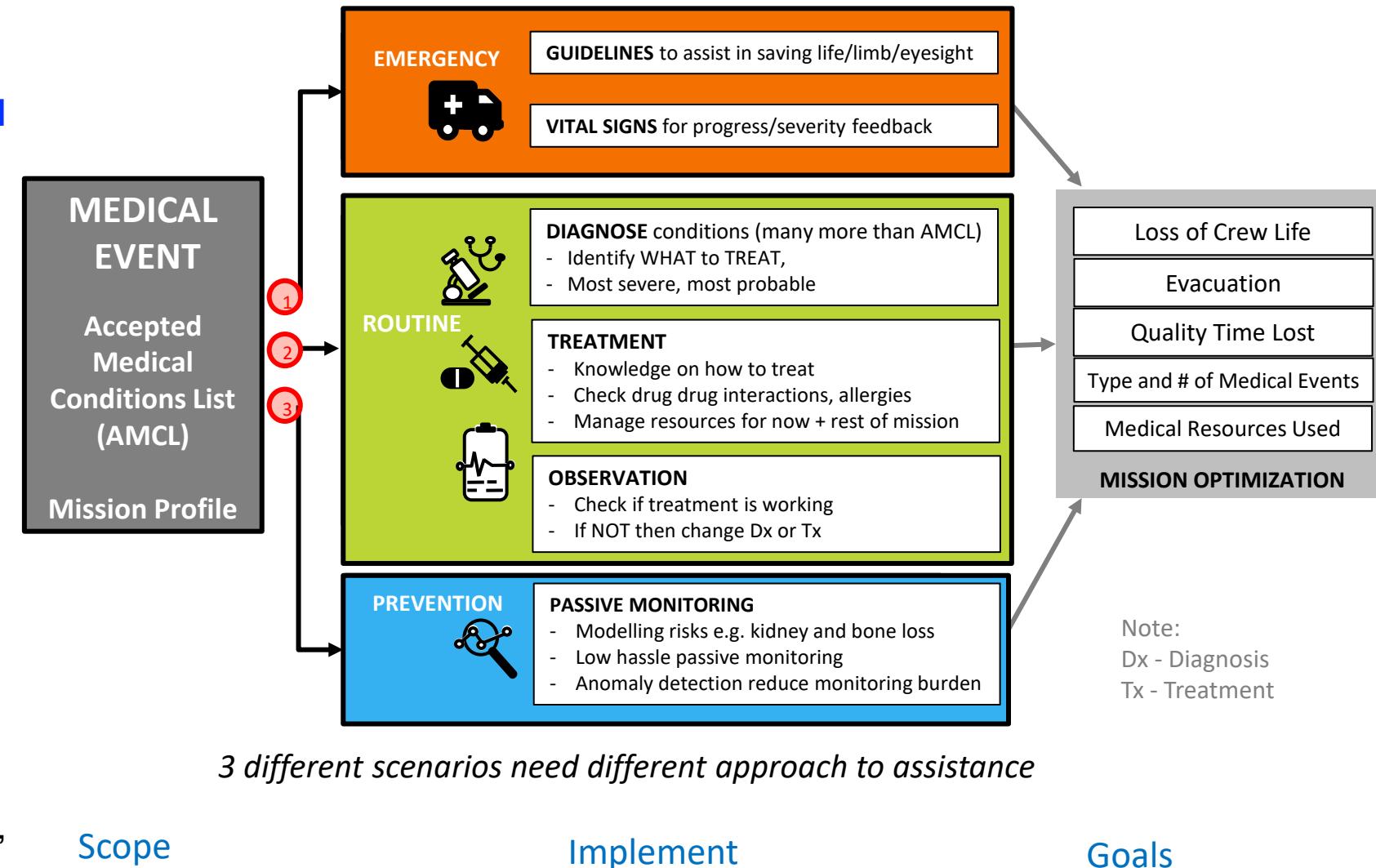


Note:
HSI – Human System Interface

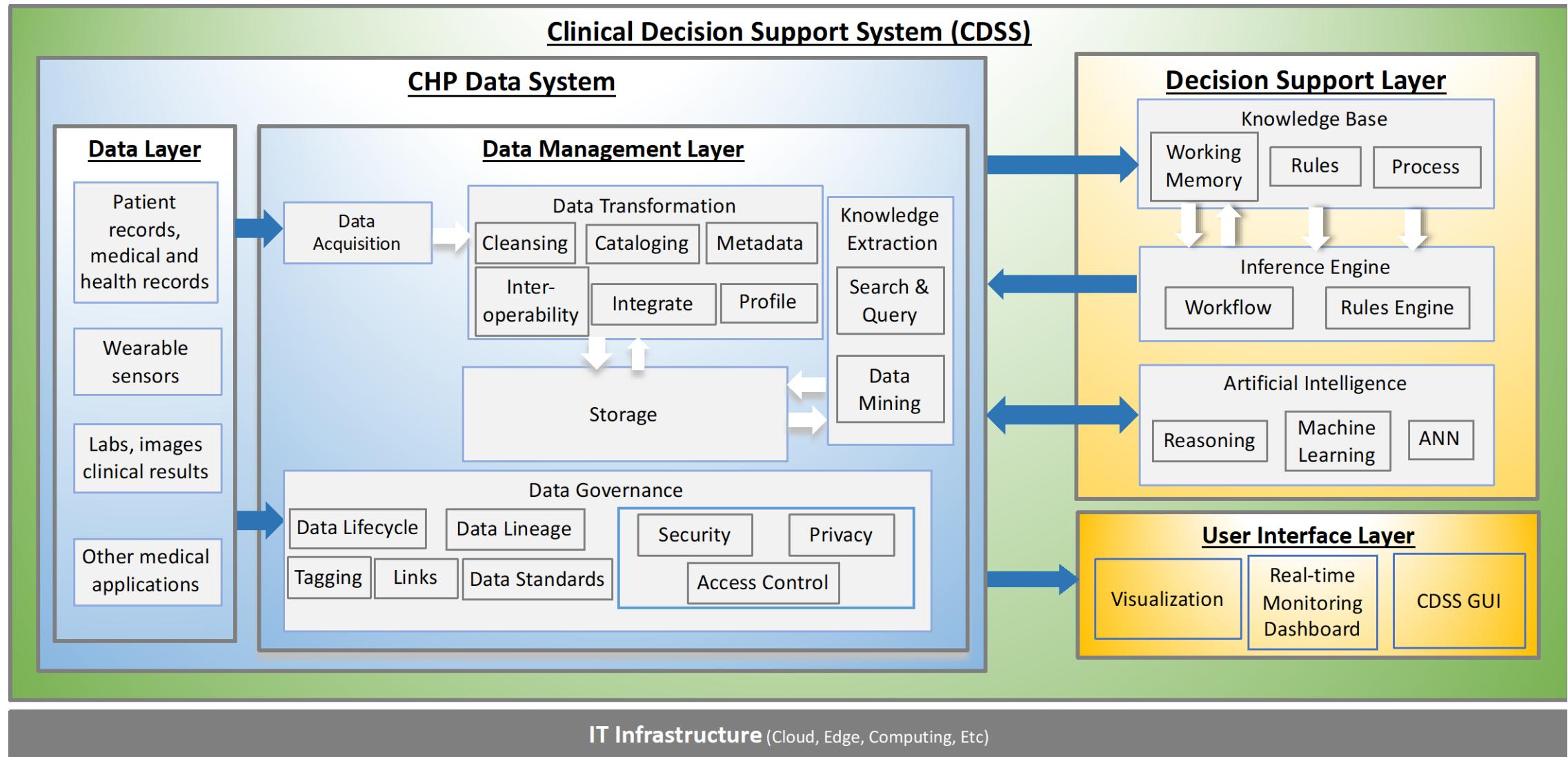
CDSS Functionality

Spacecraft CDSS Functionality

- Real-time support to **manage** anticipated and unanticipated **medical conditions**
- Act as **an assistant** to any user in dynamic, highly complex scenarios
 - Adapt to the acuity of each situation
- **Augment** the users' KSA
 - Increase standard of practice
- Operate with **communication lags**
 - With restrictions on computing power, mass, volume, and electrical power
- Reduce **cognitive load**
 - Support diagnostic and treatment workflow
 - Manage alerts
- Provide health guidance to **maintain or improve the crew's quality of life**, while preventing illness and injury



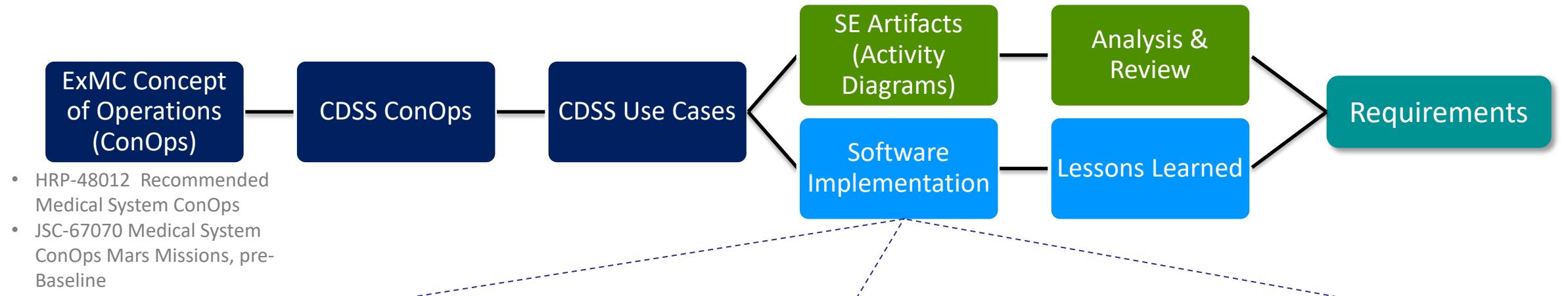
CDSS Logical Architecture



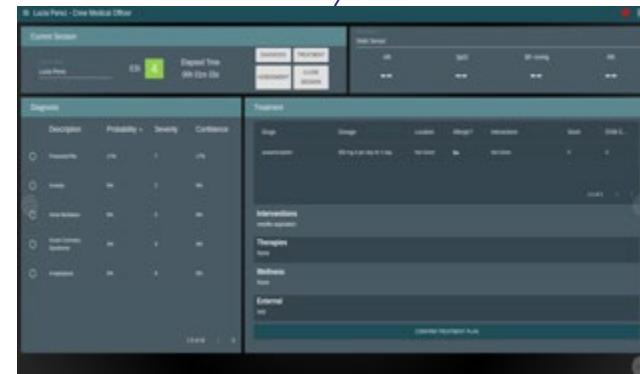
- **The CDS Project yielded several artifacts:**
 - Documentation: ConOps, technical roadmap, market survey, project plans, use cases, architecture recommendation
 - Software demonstrations
 - Model-Based Systems Engineering (MBSE) model
- **Following slides will focus on the System Engineering artifacts captured in the model**
 - ConOps
 - Activity diagrams
 - Requirements

Process to Derive Requirements

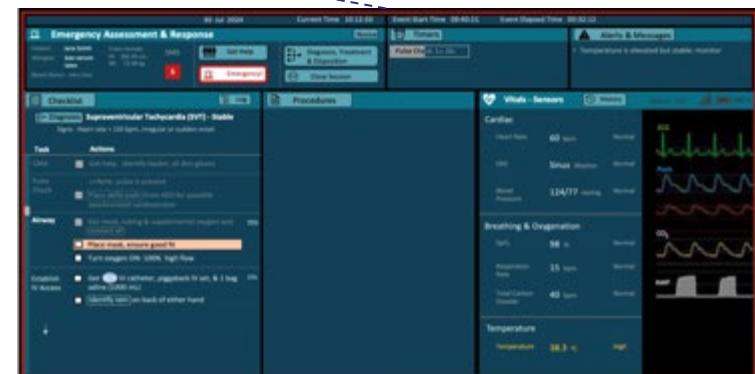
Functional Decomposition



Diagnosis



Treatment



Emergent Scenario

CDSS Model Home Page

CDSS Content:

- Project Summary
- ConOps
- Requirements
- Requirements

Development Process Document

Exploration Medical Capability Clinical Decision Support Model

CDSS Paradigm

Unlike ISS operations in LEO, future journeys travelling deeper into space will require an increased reliance on the ability to conduct Earth-Independent Medical Operations (EIMO). Depending on the orbital positions of Earth and Mars when the crew reach Mars, one-way communication delays can be more than 20 minutes [5]. These communication delays will require the crew to detect, diagnose, and treat time critical medical issues autonomously. Autonomous operation is defined here as performing self-directed clinical tasks without realtime Mission Control Center (MCC) support. In an emergency medical situation (acute and life threatening), the crew will need to react swiftly, using locally available information. Preventative and routine health care may be a hybrid system with autonomous data collection and in-vehicle decision support to assist workflow or more critically during periodic lack of communication from planetary alignment, solar wind or equipment failure. Medical inventory will also need to be used strategically in the absence of resupply missions or early return to Earth.

A physician astronaut could be included as a crewmember on a deep space mission, but even two or three physicians would not have the breadth of expertise necessary for addressing the full range of potential health-related issues on a multi-year mission. Moreover, if pre-flight crew training is viewed as a fixed resource, additional medical training before a mission means less training time devoted to other critical domains, such as extravehicular activity, spacecraft systems maintenance, or scientific research. Furthermore, there will likely be situations in flight where the CMO is the patient and requires care from clinically novice crew members. A possible solution lies in developing assistive technology and tools to increase the crew's medical Scope of Practice (medical procedures, processes and actions that an exploration crew can perform).

Model Directory

Concept of Operations (ConOps)



ConOps Home

Requirements



CDS Requirements Overview

ConOps Main Page

ConOps Content:

- Change Log
- Purpose & Scope
- Assumptions
- CDSS Overview
- Stakeholder Needs
- Goals
- Scenarios

Change and Revision Log

This Clinical Decision Support System (CDSS) Concept of Operations contained within this model is a revision of the baseline document, HRP-48033.



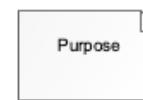
Document Change and Revision Log

Purpose & Scope

This section of the report lists the purpose, scope, change authority, document terminology, applicable documents and references. Click the icons to view the text.



Introduction



Purpose



Scope



Change Authority



Applicable Documents



Reference Documents

Mission Descriptions and Assumptions

This section provides a CDSS overview and identifies the stakeholders, the stakeholder needs, CDSS goals, and assumptions the team used to define the CDSS specified in this report.

CDSS Overview



CDSS Overview

Stakeholders and Stakeholder Needs

The sole stakeholder for this project-level ConOps is the HRP ExMC Element. However, there are multiple potential stakeholders for CDS beyond the ExMC Element insofar as Earth Independent Medical Operations (EIMO) that would include OCHMO/HTMA, MedOps, and the crew office. This ConOps also supports the main CDS project goal, which is the delivery of recommended CHP CDSS functional requirements to the ExMC Element. In addition, the CDS project addresses the ExMC gap Medical-701 within the Inflight Medical Conditions risk: Enhance medical capabilities within an exploration medical system.



Stakeholder Needs

CDSS Medical Scenarios



Personalized Nutrition



Kidney Stone



Data Input Correction During a Cognitively Rigorous Task



Cabin Atmosphere Problem Identification



Bone Health



Emergency Care by a Non-CMO



Chest Trauma with Pneumothorax



CDSS Configuration

Scenarios present a narrative that describes the actions of the actors in the medical event. Scenarios include:

- Context
- Narrative
- Highlighted Functionality
- Assumptions
- Activity Diagrams

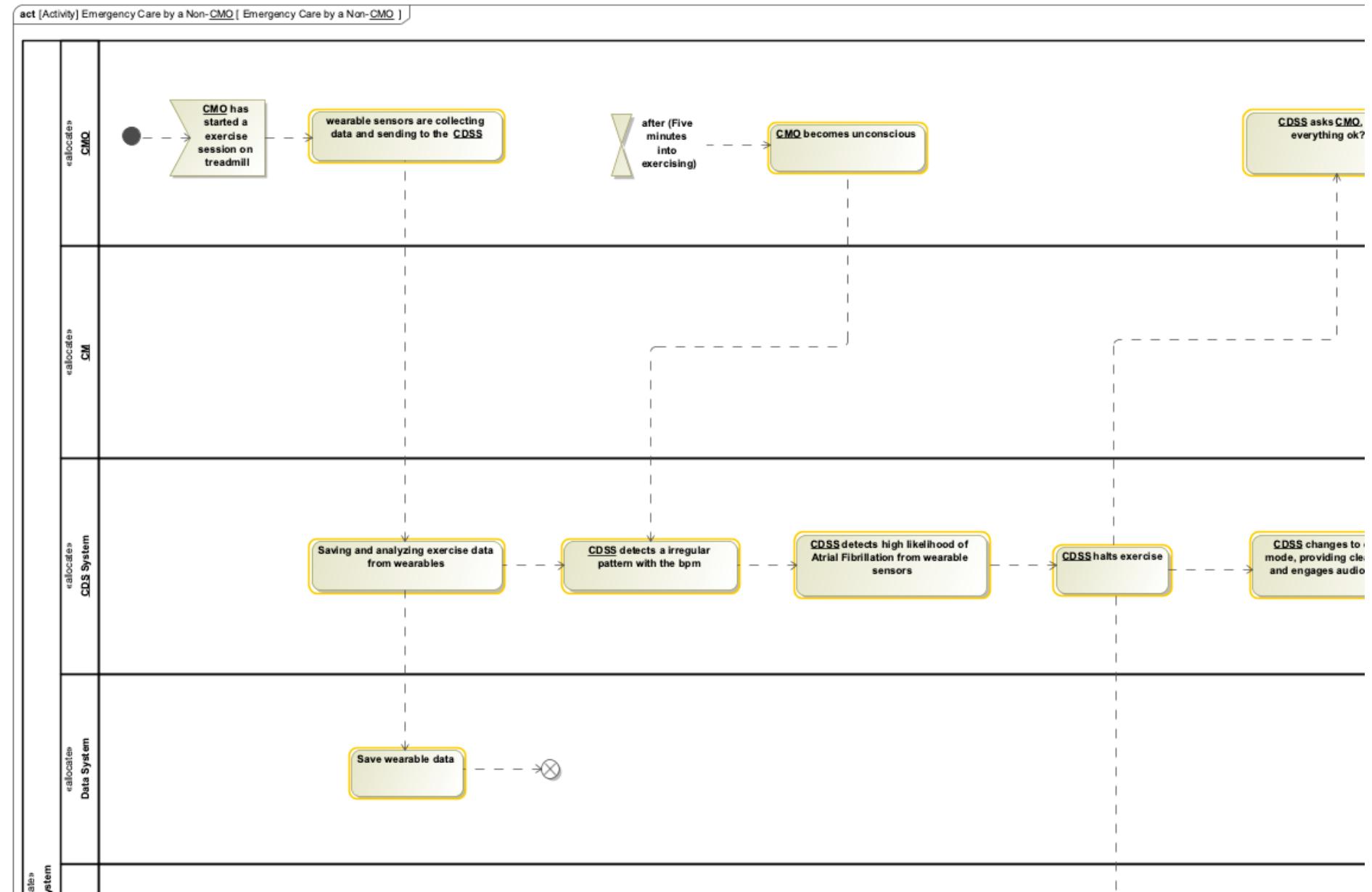
Scenario Excerpt

Narrative

Hours after exercising, a CM logs into the medical system reporting a headache. The CDSS assesses the pharmacy resources, references the CM's EHR for treatment contraindications, and recommends taking an oral nonsteroidal anti-inflammatory medication. The CM accepts the recommendation and logs consumption in the medical system. A second CM logs into the system twelve hours later and performs an exercise workout. They both finished early, and the system notices they performed 70% of today's workout load and tags the event as possible exercise intolerance. Finally, a third CM is tagged "fatigued," as suggested by their monitored eye-lid closures and speech latency via a personal computer camera that observes a crew member. For example, the CDSS results may be derived from a Percentage eye openness tracking (PERCLOS) model.

Activity Diagrams

Breakdown the scenario into discrete actions by the actors involved and identify the functionalities of the systems in the narrative.



Requirements Main Page



Requirements Content:

- Requirement Table
- Requirements with Traces to Parent Requirements
- Requirement Matrix
- CDSS Requirement Development Process Document

CDS Requirements Overview

Note: These requirements started review as NASA -STD-3001 Volume 1, Revision B and NASA -STD-3001 Volume 2, Revision C were released in 2022. Future updates to and/or use of these requirements should evaluate the requirements with respect to these standards.



SE Level 4.1 Table



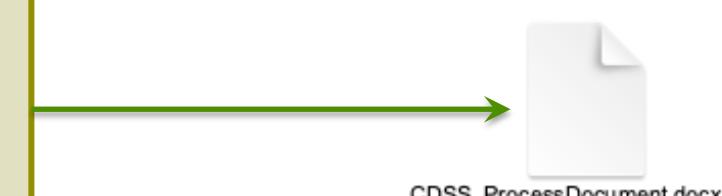
SE Level 4.1 w/ Relationships Table



SE Level 4.1 Matrix

CDSS Process Document includes:

- Project background
- Approach to:
 - Requirements development
 - Requirements tracing
 - Prototype software development
- Review processes
- Applicable and reference documents



#	Requirement Category	Requirement Subcategory	Requirement ID	CHP Requirement Level	Requirement Name	Requirement Text	Requirement Rationale	Derived From
1	Data Presentation	Data Visualization	CDSS-0001	Level 4.1	Present CDSS data	The CDSS shall provide data visualization.	The Clinical Decision Support System (CDSS) must provide results from descriptive or advanced analytics to the user. Since the CDSS will be comprised of several algebraic algorithms and artificial intelligence based models, the user will need to receive the output of those analyses visually. These analytical results are new knowledge or insights derived from the information (e.g., data). Furthermore, these results should be available on a fixed display and portable devices (e.g., laptop, tablet, phone). Screen sizes and resolution to be determined by Level 5 requirements.	 L4-Lunar-DataSys-0119 Present data
2	Data Presentation	Data Visualization	CDSS-0002	Level 4.1	Present diagnoses	The CDSS shall present a differential diagnosis.	The CDSS must provide suggested/possible diagnoses from an artificial intelligence based diagnosis model. For example, the CDSS may provide several probable diagnoses where each condition is listed with the associated probability, confidence and severity. In addition, the CDSS must support alternative diagnoses that allow the user to independently access onboard medical databases as alternate sources of information.	 L4-Lunar-DataSys-0043 Present medical data  L4-Lunar-DataSys-0048 Provide access to medical data  L4-Lunar-DataSys-0119 Present data
3	Data Presentation	Data Visualization	CDSS-0003	Level 4.1	Present treatment options	The CDSS shall present treatment options.	The CDSS must display treatment options for the diagnosed medical conditions. For example, the treatment options may be based on the resources available where pharmaceutical stock levels are presented and the caregiver may select the appropriate drug.	 L4-Lunar-DataSys-0119 Present data  L4-Lunar-DataSys-0043 Present medical data  L4-Lunar-DataSys-0048 Provide access to medical data

Requirement tables provide:

- Requirement name
- Requirement statement (e.g., The CDSS shall...)
- Rationale
- Trace(s) to parent requirements

The CDS Project concluded at the end of FY22.

**Exploration Medical Capability
Clinical Decision Support System
Architecture Recommendation**

The following will be made publicly available in 2023:

Documentation

- ExMC CDSS Architecture Recommendation (HRP-48032), Rev A
- ExMC CDSS Concept of Operations (HRP-48033)
- ExMC CDS Use Cases for CDSS (HRP-48069)

Verify this is the correct version before use
<https://hrp.sp.jsc.nasa.gov/HRP%20Pages/HRP%20Document%20Management%20System.aspx>

SysML Model

- CDS Project Systems Modeling Language (SysML) model that contains:
 - Revised CDSS concept of operations (HRP-48033)
 - Updated activity diagrams
 - Baseline CDSS requirements

September 29, 2022
Rev. A



National Aeronautics and Space Administration
Lyndon B. Johnson Space Center
Houston, Texas